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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,138	01/23/2001	Marc Alizon	2356.0010-04	2082

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/767,138	ALIZON ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

37 C.F.R. § 1.114

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicants' submission filed on 23 February, 2004, has been entered.

Status of the Claims

Claims 1-64 were canceled without prejudice or disclaimer and 65-67 amended. Claims 65-67 are currently under examination.

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 65-67 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In*

re Wertheim, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claims have been amended to recite purified HIV-1 viruses that encode variant HIV-1_{ELI} envelope glycoproteins that have specific amino acid residues (e.g., **S^{63}, E^{65}, I^{71}, I^{87}, E^{90}, D^{245}, K^{247}, and E^{526}** (claim 65); **S^{63}, E^{65}, I^{71}, I^{87}, A/E^{88}, E^{90}, D^{245}, K^{247}, I/M^{286}, Q/R^{509}, E^{526}, and K/Q^{697}** (claim 66); **S^{63}, E^{65}, A^{68}, I^{71}, I^{87}, A/E^{88}, E^{90}, A^{215}, R^{244}, D^{245}, K^{247}, I/M^{286}, Q/R^{509}, R^{519}, E^{526}, and K/Q^{697}** (claim 67)). The HIV-1 envelope is approximately 877 amino acids in length. The disclosure describes the isolation and molecular cloning of a novel HIV-1 isolate designated ELI. The nucleotide and amino acid sequences of this isolate were compared to other prototypical HIV-1 isolates (e.g., BRU, ARV-2, MAL). However, the disclosure clearly fails to provide adequate support for the currently claimed species. The specification clearly identifies the parent ELI sequence. However, the disclosure does not discuss desired or critical amino acid residues located within the ELI Env. The disclosure does not describe preferred variants of this sequence. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing. Applicants submit that the disclosure provides an adequate written description of the claimed invention.

Written Description

Claims 65-67 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claims have been amended to recite purified HIV-1 viruses that encode variant HIV-1_{ELI} envelope glycoproteins that have specific

amino acid residues (e.g., S^{63}, E^{65}, I^{71}, I^{87}, E^{90}, D^{245}, K^{247}, and E^{526} (claim 65); S^{63}, E^{65}, I^{71}, I^{87}, A/E^{88}, E^{90}, D^{245}, K^{247}, I/M^{286}, Q/R^{509}, E^{526}, and K/Q^{697} (claim 66); S^{63}, E^{65}, A^{68}, I^{71}, I^{87}, A/E^{88}, E^{90}, A^{215}, R^{244}, D^{245}, K^{247}, I/M^{286}, Q/R^{509}, R^{519}, E^{526}, and K/Q^{697} (claim 67)). The HIV-1 envelope is approximately 877 amino acids in length. The disclosure describes the isolation and molecular cloning of a novel HIV-1 isolate designated ELI. The nucleotide and amino acid sequences of this isolate were compared to other prototypical HIV-1 isolates (e.g., BRU, ARV-2, MAL). Thus, the skilled artisan would reasonably conclude that applicants were in possession of this particular isolate. The disclosure does not describe the isolation and characterization of any other HIV-1 viruses with the claimed variant ELI envelope regions, particularly those with the recited genetic variation. Thus, the skilled artisan would reasonably conclude that applicants were not in possession of the other ELI variants at the time of filing.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of HIV-1 viruses carrying $HIV\text{-}1_{ELI}$ envelope variants with the minimum requirements cited. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making

coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding

specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure form the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The claims are deficient as follows:

1) The disclosure only provides the nucleotide and amino acid sequence of a single HIV-1 ELI isolate. The disclosure does not describe any other variants of this sequence. Thus, applicants clearly did not contemplate making, isolating, and characterizing ELI envelope variants with the recited amino acid changes.

2) The disclosure fails to set forth specific ELI envelope variants. The claims recite a small number of preferred amino acids (e.g., 8, 12, or 16). However, the HIV-1 envelope is approximately 877 amino acids in length. Nothing in the disclosure would reasonably lead the skilled artisan to the currently claimed variants.

3) The disclosure fails to discuss preferred or critical molecular determinants that are required for any given variant. The claims

recite preferred amino acid positions. However, there is nothing in the disclosure that leads the skilled artisan to the currently claimed combination of amino acids.

4) The disclosure fails to provide any structural/functional correlations between accepted amino acid substitutions. The claimed invention only specifies 8, 12, or 16 amino acids from a total of approximately 877. Thus, the claims allow for amino acid permutations ranging in value between 859 to 869. Absolutely nothing in the disclosure leads the skilled to any particular variant nor can the skilled artisan readily envisage, which of the multitude of possible amino acid substitutions, applicants contemplated making and using.

5) The state-of-the-art vis-à-vis the effects of single amino acid substitutions on envelope structure and function is one of unpredictability (Wang *et al.*, 1995; Platt et al., 1997; Chen et al., 1998). Moreover, amino acid substitutions in other genes also clearly affect the replicative properties of the virus (Lee et al., 1997). Thus, the disclosure would need to provide considerable guidance in leading the skilled artisan to any particular ELI variant.

Accordingly, when all the aforementioned factors are considered *in toto*, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing. Applicants argue that the disclosure provides a sufficient written description of the claimed invention. This argument is not deemed to be persuasive for the reasons immediately set forth *supra*.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful,

the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Direct general inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

29 September, 2004